Message Text

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PAGE 01 TOKYO 04018 01 OF 02 131013Z
ACTION COME-00

INFO OCT-01 EA-12 ISO-00 EB-08 CTME-00 L-03 FTC-01
CIAE-00 INR-10 NSAE-00 ITC-01 SSO-00 INRE-00 SS-15
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----------088150 131039Z /20
O 131001Z MAR 78
FM AMEMBASSY TOKYO
TO SECSTATE WASHDC IMMEDIATE 6074

UNCLAS SECTION 01 OF 02 TOKYO 04018

PASS COMMERCE FOR ASSISTANT SECRETARY WEIL

E.O. 11652: NA
TAGS: BEXP, ETRD, JA, US
SUBJECT: TRADE FACILITATION COMMITTEE: CASE NO. 4--ABBOTT LABORATORIES

REF: TOKYO 794 (PARA 4)

1. BEGIN SUMMARY. EMBASSY HAS RECEIVED RESPONSE TO CASE NO. 4 RAISED UNDER ITEM ONE OF THE TRADE FACILITATION COMMITTEE (TFC) TERMS OF REFERENCE. WE RECOMMEND THAT, IF TIME PERMITS, CASE BE DISCUSSED DURING MARCH 14 TFC SENIOR REVIEW COMMITTEE; APPROPRIATE TALKING POINTS ARE SUGGESTED. END SUMMARY.

2. GOJ CO-CHAIRMAN OF TFC TOKYO GROUP (HANAOKA) HAS RESPONDED TO LETTER FROM U.S. CO-CHAIRMAN (BUTTON) REGARDING TFC CASE NO. 4, WHICH INVOLVED THE EFFORTS BY ABBOTT LABORATORIES TO OBTAIN APPROVAL OF THE JAPANESE MINISTRY OF HEALTH AND WELFARE (MHW) FOR THE USE OF THIRD GENERATION HEPATITIS TESTS FOR BLOOD TO BE USED IN TRANSFUSIONS. ALTHOUGH COPIES OF HANAOKA'S LETTER BEING HAND-CARRIED TO WASHINGTON BY DAVID STEBBING (EA/EP), TEXT IS CONTAINED PARA 7 BELOW TO INSURE ITS AVAILABILITY PRIOR TO MARCH 14
UNCLASSIFIED

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PAGE 02 TOKYO 04018 01 OF 02 131013Z

MEETING OF TFC SENIOR REVIEW COMMITTEE.

3. MAIN POINT OF HANAOKA RESPONSE IS THAT THE EXPERT GROUP APPOINTED BY MHW IS "NOW STUDYING THIS MATTER AND IT WILL TAKE ABOUT ONE YEAR TO DRAW A CONCLUSION..." DR. IRVIN D. SMITH, PRESIDENT OF ABBOTT K.K., IS DISAPPOINTED BUT NOT SURPRISED BY REPLY. HE HAS INDICATED TO EMBASSY THAT

PRODUCTS IN QUESTION ARE COMPLEX AND DO IN FACT REQUIRE EXTENSIVE STUDY AND TESTING. HE NOTES, HOWEVER, THAT ABBOTT FIRST SUBMITTED ITS PARTICULAR PRODUCT IN FEBRUARY 1974 AND RESUBMITTED AN IMPROVED VERSION IN MAY 1976.

4. SMITH BELIEVES THAT APPROVAL PROCESS COULD BE CONSIDERABLY EXPEDITED IF MHW WERE WILLING TO MAKE USE OF U.S. FDA TEST DATA. SUCH DATA WOULD ALSO CONFIRM THAT ABBOTT PRODUCT IS APPLICABLE TO THE JAPANESE TYPE OF HEPATITIS B, ONE OF THE QUESTIONS RAISED IN THE HANAOKA LETTER.

5. IT IS SMITH'S BELIEF THAT ONE FACTOR IN THE DELAY EVIDENCED BY MHW IS ITS DESIRE TO AFFORD JAPANESE MANUFACTURERS SUFFICIENT TIME TO DEVELOP A DIRECTLY COMPETITIVE PRODUCT. HE CANNOT BE CERTAIN, HOWEVER, THAT MHW IS PRIMARILY MOTIVATED BY THIS CONSIDERATION; MORE GENERAL BUREAUCRATIC INERTIA MAY BE INVOLVED.

6. ACTION REQUESTED: IF TIME PERMITS, IT IS RECOMMENDED THAT AT THE MARCH 14 TFC SENIOR REVIEW COMMITTEE MEETING THE FOLLOWING POINTS BE MADE: (A) WE APPRECIATE MITI'S WILLINGNESS TO TAKE UP THIS CASE WITH MHW; (B) WE ARE DISAPPOINTED THAT THE JAPANESE AUTHORITIES APPEAR NOT TO RECOGNIZE THAT DELAYS IN RESOLVING CASES SUCH AS THIS FEED THE RUMORS THAT THE JAPANESE MARKET IS A CLOSED
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ONE, RUMORS THAT THE TFC WAS ESTABLISHED TO REFUTE; (C) WE UNDERSTAND THE COMPLEXITY OF THE APPROVAL PROCESS AND THE REQUIREMENTS OF RELIABILITY, EFFECTIVENESS, SAFETY, AND QUALITY WHICH MUST BE MET BY A PRODUCT OF THIS TYPE; (D) IT HAS NOW, HOWEVER, BEEN FOUR YEARS SINCE ABBOTT LABORATORIES FIRST SUBMITTED ITS PRODUCT TO THE MINISTRY OF HEALTH AND WELFARE, AND NEARLY TWO YEARS SINCE AN IMPROVED VERSION WAS SUBMITTED; (E) BECAUSE OF THE SEVERITY OF THE HEPATITIS PROBLEM IN JAPAN, WE BELIEVE IT WOULD BE IN JAPAN'S INTEREST FOR THE MINISTRY TO CONSIDER UTILIZING TEST DATA DEVELOPED BY THE U.S. FOOD AND DRUG ADMINISTRATION IN ORDER TO ACCELERATE ITS TIMETABLE; (E) WE HOPE THAT EVERY EFFORT WILL BE MADE TO COMPLETE THE NECESSARY STUDIES AT THE EARLIEST POSSIBLE DATE IN ORDER TO DEMONSTRATE THE EFFECTIVENESS OF THE TFC PROCESS.
7. BEGIN TEXT. AS CO-CHAIRMAN OF THE TRADE FACILITATION COMMITTEE, IT IS MY PLEASURE TO RESPOND TO YOUR LETTER OF JANUARY 18 CONCERNING THE APPROVAL FOR "AUSRIA", A REAGENT FOR DETECTING THE HBS ANTIGEN PRODUCED BY ABBOTT LABORATORIES.

- 1. THE MINISTER FOR HEALTH AND WELFARE HAS NOT

- APPROVED ANY REAGENTS FOR DETECTING THE HBS
- ANTIGEN INCLUDING 'AUSRIA' AS A DRUG UNDER THE
- PHARMACEUTICAL AFFAIRS LAW.

- TO APPROVE THE REAGENTS FOR DETECTING THE HBS
- ANTIGEN, INCLUSIVE OF THE ONES USED FOR RADIO-
- IMMUNOASSAY TESTS (RIA), THE MINISTER
- CONSULTED WITH THE EXPERT GROUP IN THIS FIELD.
- THEY ARE NOW STUDYING THIS MATTER AND IT WILL
- TAKE ABOUT ONE YEAR TO DRAW A CONCLUSION FOR
- THE FOLLOWING REASONS.

- (1) THE REAGENTS MUST BE FULLY ANALYZED TO INSURE

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PAGE 01 TOKYO 04018 02 OF 02 131021Z
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INFO OCT-01 EA-12 ISO-00 EB-08 L-03 FTC-01 CIAE-00
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UNCLAS SECTION 02 OF 02 TOKYO 04018

- THEIR OWN RELIABILITY, EFFECTIVENESS, SAFETY,
- QUALITY, ETC. ESPECIALLY AS TO THE PRODUCTION,
- PRESERVATION AND CONTINUOUS SUPPLYING SYSTEM OF
- REFERENCE ANTIGEN PANELS, AS WELL AS MINIMUM
- REQUIREMENTS AND NATIONAL CONTROL TEST FOR THE
- REAGENTS, CAREFUL INVESTIGATIONS ARE REQUIRED.
- THESE STUDIES ARE QUITE LABORIOUS.
- (2) HEPATITIS B WHICH JAPANESE PEOPLE SUFFER FROM
- IS DIFFERENT FROM THE ONE IN WESTERN COUNTRIES.
- ABOUT SEVENTY PER CENT OF THE JAPANESE CARRIERS
- OF HEPATITIS B VIRUS HOLD "ADR" WHICH IS ONE OF
- THE SUB-TYPES OF THE HBS ANTIGEN, WHILE THE
- NUMBER OF THE ANTIGEN "ADR" CARRIERS IN WESTERN
- COUNTRIES IS LESS THAN ONE PER CENT.

- THEREFORE, THE IDENTICAL REAGENTS FOR DETECTING
- THE HBS ANTIGEN USED IN WESTERN COUNTRIES MIGHT

- NOT BE ALWAYS EFFECTIVE FOR THE JAPANESE CARRIERS
- OF HEPATITIS B.

- 2. WITH REGARD TO THE HBS TESTS USED BY THE JAPAN
- RED CROSS, A REVERSE PASSIVE HEMAGLUTINATION
- TEST (R-PHA) WAS ADOPTED IN APRIL 1976, AND THIS
- PROGRAM HAS BEEN CARRIED OUT UNDER THE ADMINIS-

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PAGE 02 TOKYO 04018 02 OF 02 131021Z

- TRATIVE GUIDANCE.
- 3. AT ANY RATE, THE "HEPATITIS TYPE B PROBLEM" IS
- VERY SERIOUS WITH RESPECT TO HEPATITIS OBTAINED
- AFTER BLOOD TRANSFUSIONS, INFECTION IN HOSPITALS,
- VERTICAL INFECTION AND SO ON. THE MINISTER OF
- HEALTH AND WELFARE SHALL ENDEAVOR TO STUDY THOSE
- MATTERS.

- 4. IF THERE IS ANY FURTHER QUESTION ON THIS PROBLEM,
- THE BIOLOGICS AND ANTIBIOTICS DIVISION OR EVALUA-
- TION AND REGISTRATION DIVISION THE PHARMACEUTICAL
- AFFAIRS BUREAU, THE MINISTRY OF HEALTH AND WEL-
- FARE WILL BE READY TO ANSWER. END TEXT.
- SHERMAN

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